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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,777	02/16/2001	Madhukar Matthew Thakur	THA01-C1003	5209

23973 7590 09/22/2004  
DRINKER BIDDLE & REATH  
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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1616

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/763,777	THAKUR, MADHUKAR MATTHEW	
	<b>Examiner</b>	<b>Art Unit</b>	
	D. L. Jones	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/7/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 6/7/04 wherein the specification was amended; new drawings were submitted; and the claim status is as follows: claims 1, 5, 8, and 9 amended and claim 2 canceled.

**Note:** Claims 1 and 3-9 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS**

2. The Applicant's arguments filed 6/7/04 to the rejection of claims 1-5 and 7-9 made by the Examiner under 35 USC 102, 103, and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below

### **112 Rejections**

I. The rejection of claim 1, lines 6-7 is moot in view of the new grounds of rejection below.

II. The rejections of claim 5 and 9 are WITHDRAWN for reasons of record.

### **102 Rejections**

The rejection of claims 1, 3, 4, and 7-9 is MAINTAINED under 35 USC 102(e) as being anticipated by Dean et al (US Patent No. 5,968,476) for reasons of record in the office action mailed 3/5/04 and those set forth below.

Applicant asserts that the rejection should be withdrawn on the basis that the radiolabeling moiety is not a peptide chelating moiety that forms an N4 configuration.

In independent claim 1 it is written 'chelating moiety capable of complexing with a selected radionuclide in an N4 configuration'. The phrase 'capable of' is not a positive

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claim limitation and does not require that an N4 configuration be present. If the phrase was 'a chelating moiety that complexes with a radionuclide to form an N4 configuration', then, an N4 configuration would be a positive claim limitation.

### **103 Rejections**

The rejection of claims 1, 3, 4, 7, and 8 under 35 USC 103(a) as being unpatentable over Dean et al (US Patent No. 5,968,476) in view of Kawasaki et al (Chem. Pharm. Bull., 41 (5), 975-977 (1993)) and Laudano et al (Pro. Natl. Acad. Sci., USA, 75 (7), 3085-3089 (1978)) is MAINTAINED for reasons of record in the office action mailed 3/5/04 and those set forth below.

The rejection is maintained on the same basis as that set forth in the 102 rejection section above.

## **NEW GROUNDS OF REJECTIONS**

### **112 First Paragraph Rejections**

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, 4, and 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the N4 configuration generated from the amino acid sequence Gly-(D)-Ala-Gly-Gly (page 6 of specification, lines 19-20), does not reasonably provide enablement for all N4 chelating moieties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to a composition having formulae (I) or (IIa) as set forth in independent claim 5.

(2) State of the prior art

The references of record do not indicate which compositions of formulae (I) or (IIa) are useful with the claimed invention. Likewise, the references do not indicate which specific compositions possess the N4 configuration.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claim 1 encompasses a vast number of possible compositions. Applicant's specification does not enable the public to make or use such a vast number of possible compositions and

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in addition to the fact that Sequence ID No. 1 in independent claim 1 is inconsistent with that of the specification.

(4) Level of predictability in the art

The art pertaining to the peptide compositions dyes binding to chitin-containing organisms is highly unpredictable considering the variations in the amino acid sequences could drastically alter the peptide properties. Hence, determining the various peptide containing compositions for the N4 configurations requires various experimental procedures and without guidance that is applicable to all peptide containing sequences, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

Independent claim 1 encompasses a vast number of peptide containing compositions. Applicant's limited guidance does not enable the public to prepare such a numerous amount of peptide sequences. There is no directional guidance for the specific peptide containing compositions that will generate the N4 configurations. Hence, there is no enablement for all possible permutations and combinations of the peptide containing compositions.

(6) Existence of working examples

Independent claim 1 encompasses a vast number of peptide containing compositions. Applicant's limited working examples do not enable the public to prepare such a numerous amount of peptide containing compositions. While Applicant's claims

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encompass a plethora of possible peptide compositions, the specification provides for a group of four amino acids, Gly-(D)-Ala-Gly-Gly as the chelating moiety.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible N4 chelating moieties known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

**112 Second Paragraph Rejections**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 3-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3-9: The claims as written are ambiguous because one cannot readily ascertain what Applicant intends by the phrase 'analog or peptide fragment'. In

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particular, in independent claim 1, what portion of the three amino acid sequence remains in the analog/fragment? In addition, there is no antecedent basis for Sequence ID No. 1 in the claims. The sequence that Applicant has identified as Sequence ID No. 1 in the claims is not consistent with that of the specification. Page 4, lines 14-15 of the specification Sequence ID No. 1 which is decapeptide. However, Applicant's claim 1 has only three amino acid residues, and not 10 as set forth in the specification.

#### **SPECIFICATION**

7. The disclosure is objected to because of the following informalities: In the specification on page 4, there is a typo in Seq. No. 1. In particular, 'Ana' should be 'Aba'.

1.

Appropriate correction is required.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1616

September 16, 2004